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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,701	03/30/2004	Lawrence M. Blatt	6319-4502US	7220

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EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1609	

MAIL DATE	DELIVERY MODE
07/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,701	BLATT, LAWRENCE M.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-16,20-23 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-16,20-23 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/30/04, 5/26/05, 11/9/06, 4/26/07.

DETAILED ACTION

Election/Restrictions

Applicant's cancellation of group II claims 5-8, 17-19, and 24, and amendment of claims 26 and 27, is taken as election of group I in the reply filed on 5/21/2007. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

Claims 14-16, 20-23, 25-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims are drawn to a method of treating or preventing or reducing the risk of developing SARS, comprising administering an effective amount of IFN alpha, an effective amount of IFN alpha + gamma, or an effective amount of IFN Alpha (+/- gamma) and ribavirin. The specification provides a large amount of detail on formulating and administering compositions, but no data on the effectiveness of the compositions against SARS. The claimed invention is in the unpredictable art of physiology and medicine, and the specification presents no working examples. Post-filing publications give reason to believe that interferon alpha has little or no clinical effect on SARS and that ribavirin is probably toxic (Stockman et al, Plos Medicine 3(9):e343 1525-1531, 2006; Tai, Annals of the Academy of Medicine Singapore, 36 (6):

438-443, 2007). Post-filing publications also give reason to believe that interferon gamma is probably toxic as well (Theron et al, Cytokine 32:30-38, 2005). Considering the non-existent state of the art for SARS interferon treatment at the time the invention was made, the unpredictability of the art, and the absence of working examples, it is concluded that undue experimentation would have been required to determine an effective amount of IFN alpha, IFN gamma, and ribavirin to treat or prevent or ameliorate SARS.

Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of mouse hepatitis virus infection, does not reasonably provide enablement for the full scope of coronavirus infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practise the invention commensurate in scope with these claims. These claims are broadly drawn to treatment of a coronavirus infection by adminsitering a combination of interferons alpha and gamma. The coronaviruses are a diverse group, with different species affecting different kinds of animals and causing a variety of types of disease, ranging from respiratory disease to encephalitis to hepatitis. The prior art teaches effective treatment of one species of hepatitis virus using the claimed combination (Fuchizaki et al, Journal of Medical Virology 69:188-194, 2003), thereby enabling this embodiment. However, considering the variety diseases caused by the variety of coronaviruses, one skilled in the art would not be able to predict the efficacy of this treatment against other coronavirus diseases. The specification lacks detailed guidance on treament of coronaviruses other than SARS, and, as discussed

above, this guidance is not sufficient to enable treatment of SARS. Considering the broad scope of the claims, the limited guidance in the specification, the absence of working examples, and the state of the art, it is concluded that undue experimentation would be required to practise the full scope of the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 9-12 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Fuchizaki et al (Journal of Medical Virology 69:188-194, 2003). See the Abstract and page 189, column 2, paragraph 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchizaki et al (Journal of Medical Virology 69:188-194, 2003). Fuchizaki teaches treatment of a coronavirus infection by administering a combination of alpha and gamma interferons. The reference differs from the claim in that the interferons were administered intramuscularly rather than subcutaneously. However, considering the

observed successful treatment of infection, use of an alternative conventional route of administration is seen as an obvious variation. Absent unexpected results, the invention as a whole is prima facie obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-13, 20-23, and 25-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/552020. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the treatment method of the copending application except that the copending claims are drawn to treatment of a generic virus. However, the abstract of the copending application specifically states that treatment of coronaviruses is intended.

Therefore the instant claimed treatments are not patentably distinct from the copending claimed treaments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

7/9/07

Mary E. Mosher
Primary Examiner